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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,021	11/14/2001	Joseph Manuel Fernandez	INVIT1140-3	2174

7590 10/19/2005

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/003,021

Applicant(s)

FERNANDEZ ET AL.

Examiner

Christian L. Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-43 and 45-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-43 and 45-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1652

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 08/31/2005 has been entered.
2. Claims 41-43 and 45-58 are pending and under consideration in this Office Action.
3. The rejection of claims 41-43 and 45-58 as being anticipated by Dubensky, Jr. et al. (US Patent 6,342,372) has been withdrawn in view of applicants' amendment and arguments filed 08/31/2005.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 41-43 and 45-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
Applicants' arguments filed 04/29/2005, have been fully considered but they are not persuasive. Applicants reiterate the arguments made in the response filed 10/06/2004 and that the specification describes the use of 5'CACC primers to make expression constructs. The Examiner respectfully disagrees with Applicants' position for the reasons of record as supplemented below.
The claims genus claims which encompass a genus of isolated expression vectors of any

Art Unit: 1652

sequence comprising 5'-CACC linked 5' to a start codon of any open reading frame of any nucleic acid from any biological source, wherein the ORF is linked in-frame to any polynucleotide of any nucleic acid from any biological source encoding any heterologous peptide.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states:

"Eli Lilly explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1st column, line 47 to 2nd column, line 2).

The recitation of the names "ORF" and "heterologous peptide" do not define any structural features and amino acid sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features, nucleotide and/or amino acid sequences commonly possessed by the genus. Furthermore, the claims recite minimal nucleotide sequence of CACC which is not a substantial description of the nucleotide sequence and structure of the members of the claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the claimed genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or

Art Unit: 1652

chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of isolated expression vectors of any sequence comprising 5'-CACC linked 5' to a start codon of any open reading frame of any nucleic acid from any biological source, wherein the ORF is linked in-frame to any polynucleotide of any nucleic acid from any biological source encoding any heterologous peptide.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 41-43 and 45-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubensky, Jr. et al. (US Patent 6,342,372 in view Guan et al. (EP0286239) and Gregoire et al. (J Biol Chem. 1996 Dec 20;271(51):32951-9.)

Dubensky, Jr. et al. teach an oligonucleotide primer comprising the CACC sequence (SEQ ID No. 69) linked to the 5'start codon ATG of nucleic acids encoding heterologous polypeptides, where the sequences surrounding the ATG start codon from base -9 to +1 that conform to the Kozak consensus sequence for efficient translational initiation (see entire publication, especially column 90, lines 46-58). Dubensky, Jr. et al. teach eukaryotic expression vectors that contain the above described nucleic acid have contain promoters, enhances, selection marker sequence, and origin of replication (see entire patent, especially Figures 8, 11, and 15; and column 2, line 63 to column 50, line 55). Dubensky, Jr. et al. does not teach that the expression vectors are linked to an affinity purification tag or epitope tag.

Guan et al. teach expression vectors, prokaryotic and eukaryotic host cells, and methods for making, expressing, isolating, and purifying any protein fused to the *E.coli* maltose binding

Art Unit: 1652

protein (MBP); that these methods and products are useful for purifying virtually any hybrid polypeptide molecule employing recombinant techniques; and that DNA fragments coding for the target protein and MBP are linked with DNA segment coding for a peptide which is recognized and cut by a proteolytic enzyme for purposes of purifying the protein itself (see entire publication).

Gregoire et al. teach a recombinant protein with a polyhistidine tail which was purified by immobilized metal affinity chromatography (see entire publication).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polynucleotide taught by Dubensky, Jr. et al. such that the DNA encoding the MBP and DNA encoding a peptide that can be recognized and cut by a protease as taught by Guan et al. is linked to the polynucleotide taught by Dubensky, Jr. et al. Alternatively, the polynucleotide taught by Dubensky, Jr. et al. is modified to have a DNA encoding a polyhistidine tail as taught by Gregoire et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to express and purify recombinant proteins encoded by the modified polynucleotide taught by Dubensky, Jr. et al.

Conclusion

8. No claim is allowed.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1652

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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